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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/308,223 08/12/99 KALLMEYER

G P8341-9011

EXAMINER

HM12/0119

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NICKOL, G

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

01/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/308,223

Applicant(s)

KALLMEYER ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 16-18, 25, 28, 31, 32, 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is vague and indefinite for reciting "proteinaceous pharmaceutical auxiliary additives" as the metes and bounds of the claim cannot be determined. The specification (page 6, 1st paragraph) discloses that proteinaceous pharmaceutical auxiliary substances include serum albumin, however it is not known what other molecules are excluded or included as a proteinaceous pharmaceutical auxiliary additive, i.e. such as the amino acids included in the lyophilizate disclosed on page 11 of the specification.

Claim 16 is vague and indefinite for reciting "isotonizing" agent as the metes and bounds of the claim cannot be determined. The specification does not clearly define what can be included or excluded as an isotonizing agent nor as a buffering agent.

Claims 17 and 18 are vague and indefinite for reciting "at least three months" as the metes and bounds cannot be determined. The specification does not clearly define an upper limitation.

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Claims 17 and 18 are further vague and indefinite for reciting “of about” as the metes and bounds cannot be determined. The specification does not clearly define the limits of temperature stability.

Claim 25 is vague and indefinite for reciting “monomer unit”. The specification does not define what is included or excluded as a monomer as it pertains to various antibodies, i.e. a single antibody, a heavy chain, a light chains, or a unit composed of heavy and light chains or the likes thereof.

Claims 31 and 32 are vague and indefinite for reciting “up to” as the metes and bounds of the claim cannot be determined.

Claims 28 and 34 are vague and indefinite for reciting “physiologically acceptable” as the metes and bounds of the desired solution cannot be determined. The specification discloses water (page 13, 2nd paragraph) as a solute for injection but does not mention what is included or excluded as a physiological acceptable solution.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13,15,16,19,20,23,24,25,27,28, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Chuntharapai et al.

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Chuntharapai et al teach a lyophilizate consisting essentially of a monoclonal antibody, a sugar (glucose), at least one amino acid (lysine), a surfactant (Tween), and an inorganic acid as a buffering agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-24 and 26-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chuntharapai et al in view of Michaelis et al in further view of Phillips et al.

Chuntharapai et al teach as set forth above.

Chuntharapai does not teach a lyophilizate essentially free of polyethylene glycols and/or proteinaceous pharmaceutical auxiliary additives, storage-stable for a time period of at least three months at a temperature of about 4-12°C or a temperature of about 18-23°C. Chuntharapai do not teach a lyophilizate comprising one of sucrose, lactose, maltose, cellobiose, gentiobiose, isomaltose, trehalose, glucosamine, N-methyl-glucosamine, galactosamine and neuraminic acid. Further, Chuntharapai does not teach the liquid pharmaceutical composition comprising the lyophilizate as having the following: a pH value of 5-8, 1-10mg/ml of antibody, 0.05-0.5mg/ml of surfactant. Lastly, Chuntharapai does not teach a monoclonal or polyclonal antibody directed against the antigens listed in Claim 26.

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Michaelis et al teach a lyophilizate with medicinal advantages essentially free of polyethylene glycols and/or proteinaceous pharmaceutical auxiliary additives containing N-methyl glucosamine and maltose at a pH between 5-8 (column 11, table 6) which is storage-stable for at least three months at a temperature of about 4-12⁰C or a temperature of about 18-23⁰C (column 11, table 7). Further, Michaelis et al teach optimal concentrations of lyophilizate preparations including 1-10mg/ml of protein (column 2, line 36), up to 200mg/ml of sugar (column 4, line 1), up to 100mg/ml of amino acid (column 4, line 20), and 0.05-0.5mg/ml of surfactant (column 3, line 3).

Phillips et al teach that as of 1989, the lyophilization of therapeutic antibodies was art-known.

It would have been prima facie obvious to one of ordinary skill in the art to optimize the lyophilizates of Chuntharapai et al as taught by Michaelis et al in order to obtain the medicinal advantages taught by Michaelis et al. Further, it would have been obvious to do so with any therapeutically or diagnostically useful antibody including those of claim 26, given the art-known advantages of lyophilized antibodies as taught by Phillips et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on 703-308-2731. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

GBN
January 18, 2000


YVONNE EYLER, PH.D
PRIMARY EXAMINER